

WE CLAIM:

1. A process for preparing an uncoated sumatriptan tablet for oral administration, the process comprising the steps of:

granulating sumatriptan or a pharmaceutically acceptable salt with one or more diluents and/or binders to form granules;

mixing the granules with one or more pharmaceutically acceptable excipients to form a mixture; and

compressing the mixture to form a tablet.
2. The process according to claim 1, further comprising wax polishing the tablet.
3. The process according to claim 1, wherein granulating comprises dry mixing the one or more diluents and/or binders with sumatriptan and granulating with an aqueous and/or a non-aqueous solvent.
4. The process according to claim 1, wherein the sumatriptan is granulated with an aqueous and/or a non-aqueous solution or a suspension of one or more diluents and/or binders.
5. The process according to claim 3 or 4, wherein the aqueous solvent comprises water.
6. The process according to claim 3 or 4, wherein the non-aqueous solvent comprises one or both of alcohol and isopropyl alcohol.
7. The process according to claim 1, wherein the pharmaceutically acceptable salt comprises one or more of hydrochloride, hydrobromide, sulphate, nitrate, phosphate, formate, mesylate, citrate, benzoate, fumarate, maleate, tartrate and succinate salts.
8. The process according to claim 7, wherein the pharmaceutically acceptable salt comprises succinate (1:1).
9. The process according to claim 1, wherein the one or more diluents comprises one or more of calcium carbonate, calcium phosphate-dibasic, calcium phosphate-tribasic,

calcium sulfate, cellulose-microcrystalline, cellulose powdered, dextrates, dextrans, dextrose excipients, fructose, kaolin, lactitol, lactose, mannitol, sorbitol, starch, starch pregelatinized, sucrose, sugar compressible, and sugar confectioners.

10. The process according to claim 9, wherein the diluent comprises lactose.
11. The process according to claim 1, wherein the binder comprises one or more of methyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, polyvinylpyrrolidone, gelatin, gum arabic, ethyl cellulose, polyvinyl alcohol, pullulan, pregelatinized starch, agar, tragacanth, sodium alginate, propylene glycol, and alginate.
12. The process according to claim 11, wherein the binder comprises hydroxypropyl methylcellulose.
13. The process according to claim 1, wherein the pharmaceutically acceptable excipient comprises one or more of diluents, binders, disintegrants, lubricants, coloring agents, and flavoring agents.
14. The process according to claim 13, wherein the disintegrant comprises one or more of low substituted hydroxypropyl cellulose, carboxymethyl cellulose, calcium carboxymethyl cellulose, sodium carboxymethyl cellulose, croscarmellose sodium, starch, crystalline cellulose, hydroxypropyl starch, and partially pregelatinized starch.
15. The process according to claim 14, wherein the disintegrant comprises croscarmellose sodium.
16. The process according to claim 14, wherein the lubricant comprises one or more of stearic acid, magnesium stearate, calcium stearate, talc, hydrogenated castor oil, sucrose esters of fatty acid, microcrystalline wax, yellow beeswax, and white beeswax.
17. The process according to claim 16, wherein the lubricant comprises one or both of talc and magnesium stearate.

18. The process according to claim 2, wherein the wax polishing comprises spraying a solution or suspension of wax onto the tablet.
19. The process according to claim 2, wherein the wax polishing comprises sprinkling a powder grade wax onto the tablet.
20. The process according to claim 2, wherein wax material comprises one or more of shellac, modified shellac, opaglos II, carnuba wax, bees wax, paraffin wax, and polyethylene glycol.
21. The process according to claim 20, wherein the wax material comprises modified shellac.
22. The process according to claim 2, wherein the total weight build up of wax polishing solid comprises up to about 10% w/w, based on the total weight of the tablet.
23. The process according to claim 1, further comprising granulating and/or mixing a second active pharmaceutical ingredient with the sumatriptan.
24. A process for preparing uncoated sumatriptan tablets for oral administration, the process comprising the steps of:

spraying a solution or suspension of sumatriptan or a pharmaceutically acceptable salt in a solvent onto inert cores to form a first layer;

blending the core having the first layer with one or more pharmaceutically acceptable excipients to form a blend; and

compressing the blend to form a tablet.
25. The process of claim 24, wherein the solution or suspension of sumatriptan in a solvent further includes one or more diluents and/or binders.
26. The process of claim 24, further comprising creating a second layer on the cores having the first layer, the second layer comprising one or more diluents and/or binders.

27. The process of claim 25, further comprising creating a second layer on the cores having the first layer, the second layer comprising one or more diluents and/or binders.
28. The process of claim 24, further comprising polishing the tablet.
29. The process of claim 28, wherein polishing the tablet comprises sprinkling a fine powder grade of a wax material on the tablet.
30. The process of claim 28, wherein polishing the tablet comprises spraying a solution or suspension of a wax material in organic solvent onto the tablet.
31. The process according to claim 24, wherein the inert core comprises one or more of a sugar sphere, a non-pareil seed, cephers, or a pharmaceutically acceptable inert insoluble, soluble or swellable material.
32. The process according to claim 31, wherein the pharmaceutically acceptable inert core comprises a non-pareil seed.
33. The process according to claim 31, wherein the insoluble inert material comprises one or more of sand, silicon dioxide, glass, microcrystalline cellulose, a plastic, and polystyrene.
34. The process according to claim 31, wherein the soluble inert material comprises one or more of a sugar, glucose, mannitol, lactose, xylitol, dextrose, and sucrose.
35. The process according to claim 31, wherein the swellable inert material comprises hydroxypropyl methylcellulose.
36. The process according to claim 24, further comprising spraying and/or blending a second active pharmaceutical ingredient with the sumatriptan.
37. A wax polished dosage form of sumatriptan, the dosage form comprising:

sumatriptan or a pharmaceutically acceptable salt;

one or more pharmaceutically acceptable carriers or excipients; and

a wax polish on the dosage form.

38. The wax polished dosage form of sumatriptan of claim 37, wherein the wax polish comprises a wax material.
39. The wax polished dosage form of sumatriptan of claim 37, wherein the wax material comprises one or more of shellac, modified shellac, opaglos II, carnuba wax, bees wax, paraffin wax, polyethylene glycol.
40. The wax polished dosage form of sumatriptan of claim 37, wherein the total weight buildup of wax material is up to 10% w/w, based on the weight of tablet.
41. The wax polished dosage form of sumatriptan of claim 37, wherein the dosage form is a tablet or capsule.
42. The wax polished dosage form of sumatriptan of claim 37, wherein the dosage form is a tablet.
43. The wax polished dosage form of sumatriptan of claim 37, wherein the one or more pharmaceutically acceptable excipients includes one or more of diluent, binder, disintegrant, lubricant/glidant, coloring agent and flavoring agent.
44. The wax polished dosage form of sumatriptan of claim 37, further comprising a second active pharmaceutical ingredient in the dosage form.
45. An uncoated, wax polished sumatriptan tablet comprising:

a tablet core comprising about 10-200 mg of sumatriptan or a physiologically acceptable salt and one or more pharmaceutically acceptable carriers or excipients, and

a wax polish on the tablet core,

wherein the wax polish comprises an amount of from about 2 to 10% weight/weight of the tablet.
46. An uncoated, taste-masked sumatriptan tablet for oral administration, the uncoated tablet comprising:

an intragranular portion comprising granules of sumatriptan or a pharmaceutically acceptable salt and one or more diluents and/or binders present in a sufficient amount to cause taste-masking of the sumatriptan or pharmaceutically acceptable salt; and

an extragranular portion comprising one or more pharmaceutically acceptable excipients around the intragranular granules.

47. The uncoated, taste-masked sumatriptan tablet of claim 46, wherein the one or more diluents and/or binders in the intragranular portion completely encapsulate the sumatriptan or physiologically acceptable salt.
48. The uncoated, taste-masked sumatriptan tablet of claim 46, wherein the one or more diluents and/or binders in the intragranular portion substantially encapsulate the sumatriptan or physiologically acceptable salt.
49. The uncoated, taste-masked sumatriptan tablet of claim 46, wherein the intragranular portion and/or the extragranular portion further comprises a second active pharmaceutical ingredient.
50. A method of treating or prophylactically treating a human suffering from a migraine condition, the method comprising orally administering a wax polished dosage form of sumatriptan, the oral dosage form comprising:

sumatriptan or a physiologically acceptable salt and a pharmaceutically acceptable carrier or excipient;

one or more pharmaceutically acceptable carriers or excipients; and

a wax polish on the dosage form.
51. The method of treating of claim 50, wherein the tablet comprises about 10 mg to 200 mg of sumatriptan.
52. A method of treating or prophylactically treating a human suffering from a migraine condition, the method comprising orally administering an uncoated, taste-masked tablet of sumatriptan, the uncoated tablet comprising:

an intragranular portion comprising granules of sumatriptan or a pharmaceutically acceptable salt and one or more diluents and/or binders present in a sufficient amount to cause taste-masking of the sumatriptan or pharmaceutically acceptable salt; and

an extragranular portion comprising one or more pharmaceutically acceptable excipients around the intragranular granules.

53. The method of treating of claim 52, wherein the tablet comprises about 10 mg to 200 mg of sumatriptan.
54. The method of treating of claim 52, wherein the intragranular portion and/or the extragranular portion further comprises a second active pharmaceutical ingredient.